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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,197	12/27/2001	Rohini Ramesh Joshi	4347-4000	8255

7590 08/04/2003
Morgan & Finnegan L.L.P.
Maria C.H. Lin
345 Park Avenue
New York, NY 10154-0053

EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 08/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/033,197	Applicant(s) JOSHI ET AL.	
	Examiner Irene Marx	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4,5</u> . | 6) <input type="checkbox"/> Other: |

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The application should be reviewed for errors and conformity with domestic practice.

It is noted that the microorganism(s) required to practice the claimed invention are currently available from the ATCC. It appears that the microorganism(s) should remain available to the public beyond the effective life of the patent. Any information to the contrary which comes to applicants' attention during the prosecution of this application must be inserted into the record or otherwise be brought to the attention of the Office by applicants.

The complete name and address of the depository should be inserted in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague, indefinite and confusing in that the definitions of X and Y-Z are inconsistent and contradictory for formula I and III. It is unclear that the reaction with any enzyme or any whole cell in a buffer will cause all the biotransformations as stated.

Claim 1 is further vague, indefinite and confusing in that the designation of compound of formula I as " \pm 2-aza-bicyclo[2,2,1]hept-5-en-3-one" pertains to a specific compound. It is also noted that claim 15 requires the process to have a specific optical purity. It is apparent that a stereoselective process is obtained only with ATCC 21285 and not with any cell or enzyme.

The use of parenthesis in the claims renders the claims ambiguous as to what is intended. The removal of parenthesis is required to properly provide positive limitations in the claims.

Also, the term "formula", first occurrence is typed in a confusing and unclear fashion.

In claim 1, the use of dashes for bonds in this claim is inconsistent. The meaning of "Ph" should be set forth. Commas appears to be missing in the listing of moieties of Y-Z and at line 2 of the claim.

Claim 2 is confusing and appears grammatically incorrect in the recitation of "the microorganism or enzyme is from the *Bacillus*, *Klyuvera* or *Escherichia*."

In claim 3, the correct name is "*Klyuvera citrophila*".

Claims 3 and 4 are inconsistent and contradictory in that ATCC 21285 is either "*Klyuvera citrophila*" or "*Klyuvera* sp.", but not both.

Claims 1-14 are incomplete in the absence of a recovery step for the product produced.

While there is no specific rule or statutory requirement which specifically addresses the need for a recovery step in a process of preparing a composition, it is clear from the record and would be expected from conventional preparation processes that the product must be isolated or recovered. Thus, the claims fail to particularly point out and distinctly claim the "complete" process since the recovery step is missing from the claims. The metes and bounds of the claimed process are therefore not clearly established or delineated.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at

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the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Dawson *et al.* (U.S. Patent No. 6,340,587).

The claims are directed to a process of making optically active 2-azabicyclo[2,2,1]hept-5-en-3-one from the racemic mixture using a whole cell or enzyme in the process using an organic solvent at conventional process conditions

Dawson *et al.* disclose a process of making optically active 2-azabicyclo[2,2,1]hept-5-en-3-one from the racemic mixture using a whole cell or enzyme in the process and in the presence of an organic solvent at conventional process conditions. See, e.g., Example 1.

Claims 1-2 and 5-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dawson *et al.* taken with Bernegger-Egli *et al.* and Evans *et al.* (EP 0442064).

The claims are directed to a process of making optically active 2-azabicyclo[2,2,1]hept-5-en-3-one from the racemic mixture using a whole cell or enzyme in the process using an organic solvent at conventional process conditions.

Dawson *et al.* disclose a process of making optically active 2-azabicyclo[2,2,1]hept-5-en-3-one from the racemic mixture using a whole cell or enzyme in the process and in the presence of an organic solvent in phosphate buffer at conventional process conditions. See, e.g., Example 1.

The reference differs from the claimed invention in the use of various buffers and organic solvents in the process and in the use of chlorinated solvents or alkyl acetate in the extraction. However, the substitution of phosphate buffer with other conventional buffers would have been an obvious expedient in the art at the time the claimed invention was made. In addition, Bernegger-Egli teach a similar enzymatic process wherein various organic solvents may be used, such as methanol, ethanol, butanol (See, e.g., page 3, lines 24-26). Even though acetone is not specifically mentioned it is well known in this art as a suitable organic solvent useable in enzymatic reactions

Moreover, the use of chlorinated solvents such as dichloromethane is routine in this art, as adequately demonstrated by Evans *et al.* The substitution of other chlorinated

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solvents or a conventional solvent such as ethyl acetate for optimization purposes would have been within the purview of the ordinary artisan in this art at the time the claimed invention was made.

It would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Dawson *et al.* in the preparation of optically active 2-aza-bicyclo[2,2,1]hept-5-en-3-one by using further solvents in the reaction medium and further extraction solvents as suggested by the teachings of Bernegger-Egli *et al.* and Evans *et al.* for the expected benefit of optimizing the yield of optically active 2-aza-bicyclo[2,2,1]hept-5-en-3-one, a compound useful as an intermediate in the production of valuable antiviral compounds.

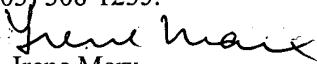
Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Claims 3 and 4 are free of the art would be allowable upon resolution of all issues under 35 U.S.C § 112.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.


Irene Marx
Primary Examiner
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